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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,187	01/13/2006	Rhonda Hansen	20366-124US1	3472

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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
10/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,187	HANSEN, RHONDA	
	Examiner	Art Unit	
	TERRA C. GIBBS	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-29 and 31-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-29 and 31-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/16/09 and 8/28/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's Amendment and Remarks filed June 16, 2009.

New claims 38 and 39 are acknowledged. Claims 21 and 32 have been amended.

Claims 21-29 and 31-39 are pending in the instant application.

This application contains SEQ ID NO:510 as recited in claim 36 drawn to an invention nonelected with traverse in the reply filed on February 8, 2008. A complete reply to the final rejection must include cancellation of nonelected subject matter or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Claims 21-29 and 31-39 and SEQ ID NO:508 as recited in claim 36 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

Applicant's information disclosure statement filed June 16, 2009 is acknowledged. The submission is in compliance with the provisions of 37 CFR §1.97. Accordingly, the Examiner has considered the information disclosure statement, and a signed copy is enclosed herewith.

Applicant's information disclosure statement filed August 28, 2009 is acknowledged. The submission is not fully compliant with the provisions of 37 CFR

§1.97, which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It is noted that an English translation of Citation No.37, EP-0345242-A2 has not been provided. Therefore, Citation No.37, EP-0345242-A2 has not been considered on the merits. Furthermore, a copy of Citation No.54, WO 93/19191-A1 cannot be located in the file.

Accordingly, the Examiner has considered the information disclosure statement filed August 28, 2009, and a signed copy is enclosed herewith. However, it has been indicated that Citation No.37, EP-0345242-A2 and Citation No.54, WO 93/19191-A1 have not been considered as the references have been lined through.

Priority

In the previous Office Action mailed January 16, 2009, the instant claims were afforded priority to PCT/US03/00657, filed January 8, 2003 because Provisional Application 60345637 failed to provide adequate support in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, the term, "anti-cancer" could not be found anywhere in Provisional Application 60345637.

In Applicant's Amendment to the claims filed June 16, 2009, Applicants have amended claims 21 and 32 to remove the term, "anti-cancer". In view of Applicant's Amendment, the instant claims have been afforded priority to Provisional Application 60345637, filed January 8, 2002.

Claim Rejections - 35 USC § 103

In the previous Office Action mailed January 16, 2009, claims 21-29 and 31-34 and 37 were rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/21994 ('994). **This rejection is maintained** for the reasons of record set forth in the previous Office Action mailed January 16, 2009. It should be noted that newly submitted claims 38 and 39 are also rejected under 35 U.S.C. 103(a) as being unpatentable over WO '994.

Response to Arguments

In response to this rejection, Applicants argue that the instant claims relate to DKFZ protein, where the specification indicates that DKFZ is also known as VMP1, or vacuole membrane protein 1. Applicants contend that, in contrast, the '994 application relates to the "Human Vesicle Membrane Protein-Like Proteins" known as VMP1, VMP2, and VMP3. Applicants argue that despite the similar names, these are distinct proteins, as there is no significant sequence similarity between the two proteins, and therefore, the cited reference fails to teach the methods as claimed.

These arguments and contentions have been fully considered, but are not found persuasive because it should be noted that the instant claims are void of a specific sequence. Therefore, it cannot be said that the DKFZ, also known as VMP1 of Applicant's claimed invention is different or distinct from the VMP1 of the '994 application.

Furthermore, Applicant is reminded that during patent examination, the claims

are given the broadest reasonable interpretation consistent with the specification. See MPEP § 2111-2116.01. As Applicants note above, the instant specification discloses that DKFZ is also known as VMP1. Therefore, given its broadest reasonable interpretation, and absent a sequence for DKFZ, also known as VMP1 of Applicant's invention, the Examiner has included the disclosure of the '944 application to embrace DKFZ, also known of VMP1 of the claimed invention.

In view of the foregoing, the '994 application teaches detecting a difference in biological activity and expression level of DKFZ expressed by a cell can be used in methods of identifying cancer therapeutic agents.

Regarding newly submitted claims 38 and 39, the '994 application teaches that VMP1 is expressed in gastrointestinal, lung, heart, breast, prostate, and brain tissues, in hematopoietic and smooth muscle tissues, and in fetal tissues (see page 30, lines 25-29). The '994 application goes on to teach that VMP1 antagonists include proteins, nucleic acids, and antibodies can be used to treat diseases and conditions associated with the expression and activity of VMP1. See pages 30-41, for example.

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In the previous Office Action mailed January 16, 2009, claims 35 and 36 were rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/21994 ('994) as applied to claims 21-29 and 31-34 and 37 above, and further in view of Dusetti et al. (Biochemical and Biophysical Research Communications, 2002 Vol. 290:641-649), and U.S. Patent No. 6,844,325 ('325). **This rejection is maintained** (in part) for the

reasons of record set forth in the previous Office Action mailed January 16, 2009.

Response to Arguments

In response to this rejection, Applicants argue that as an initial matter, Dusetti et al. is not available as prior art. This argument has been fully considered, and is found persuasive. It is noted that in view of Applicant's Amendment to the claims filed June 16, 2009, the instant claims have been afforded priority to Provisional Application 60345637, filed January 8, 2002. Therefore, Dusetti et al. is not available as prior art. However, as detailed below, the claims are still rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/21994 ('994) as applied to claims 21-29 and 31-34 and 37 above, and further in view of U.S. Patent No. 6,844,325 ('325).

Applicants next argue that the '325 application fails to remedy the deficiency of the '994 application since the '325 application relates primarily to various clones over-expressed in breast cancer tumor tissue, none of which include DKFZ expressed by a cell which can be used in methods of identifying cancer therapeutic agents. Applicants contend that in view of these arguments, the Office has failed to establish a *prima facie* case for obviousness of claims 35 and 36.

These arguments have been fully considered, but are not found persuasive. First, Applicant is reminded that the Examiner has interpreted DKFZ also known as VMP1 broadly to included and embrace VMP1 as disclosed in the '944 application.

Second, Applicant is directed to the '994 application which teaches VMP1 antagonists. Specifically, '994 teach that VMP1 antagonists include nucleic acids (see

page 11, lines 29-32). '994 teach that a host cell may be used to modulate the expression of VMP1 (see page 27, lines 16-25). '994 also teaches that genes encoding VMP1 can be turned off by transforming cells or tissues with antisense constructs (see page 36, lines 10-28). The '994 application also teaches the identification of molecules which interact with VMP where candidate molecules are tested and assayed for their ability to inhibit VMP activity and expression (see XIII at page 59, for example). Also, see pages 35-37, and 44-49.

The '994 application does not teach an antisense comprising a nucleotide sequence comprising at least 12 contiguous nucleotides of SEQ ID NO:513 (as required by claim 35), or a nucleotide sequence comprising SEQ ID NO:508 of Applicant's invention (as required by claim 36).

However, the prior art teaches that SEQ ID NO:508 of Applicant's invention could be used as an antisense polynucleotide. For example, the '325 application teaches a cDNA sequence of clone 21053 (see SEQ ID NO:458). '325 also teach that cDNAs of their invention are in the antisense orientation. It is noted that SEQ ID NO:458 taught by '325 comprises the entire sequence of SEQ ID NO:508 of Applicant's invention and therefore meets the limitations of claim 36. It is also noted that SEQ ID NO:458 disclosed by '325 comprises at least 12 contiguous nucleotides of SEQ ID NO:513 of Applicant's and therefore meets the limitations of claim 35.

As discussed in the previous Office Action mailed January 16, 2009, the '325 application is silent regarding whether the cDNA sequence represented by SEQ ID NO:458 could be used as an antisense to inhibit DKFZ expression. However, the

burden of establishing whether the prior art antisense cDNA could be used to inhibit gene expression under generally any assay conditions falls to Applicant. See MPEP 2112.01, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433." See also MPEP 2112: "[T]he PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [her] claimed product." The MPEP at 2112 citing *In re Fitzgerald* 205 USPQ 594. 596, (CCPA 1980), quoting *In re Best* 195 USPQ 430 as per above. Therefore, it falls to Applicant to determine and provide evidence that prior art antisense cDNA disclosed by '325 would or would not inhibit DKFZ gene expression as instantly claimed.

Furthermore, Applicant is directed to their Specification which explicitly discloses that regarding antisense molecules,

> "The size of the segment over which there is sequence identity can vary depending upon the size of the subject polynucleotide. In general, however, there is substantial sequence identity over at least 15, 20, 25 … nucleotides"

In view of the foregoing, when all the evidence is considered, the totality of the rebuttal evidence of non-obviousness fails to outweigh the evidence of obviousness made of record. Thus, it is maintained that the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was filed.

Applicant's Amendment filed June 16, 2009 necessitated the new ground(s) of objection presented below:

Claim Objections

Claim 21 is objected to because of the following informalities: The preamble of claim 21 is grammatically incorrect because it incorrectly recites, "A method of identifying ***an*** cancer therapeutic agent". Appropriate correction is required.

Applicant's amendment necessitated the new ground(s) of objection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached from 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James “Doug” Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

October 7, 2009
/Terra Cotta Gibbs/

/JD Schultz/
Supervisory Patent Examiner, Art Unit 1635